510(K) SUMMARY

JUL 11 2008

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K071677

1. **Submitter's Identification:** Therapeutic Innovations, 541 Buttermilk Pike, Suite 309, Crescent Springs, KY 41017

Date Summary Prepared: June 6, 2008

Contact Persons: Bruce D. Rowe

2. **Name of the Device:**

a. TRADE NAME: SRT II® Muscle Stimulator
b. CLASSIFICATION NAME: Muscle Stimulator
c. PRODUCT CODE: IPF

3. **Common or Usual Name:** Powered Muscle Stimulator

4. **Predicate Devices Information:**

K982317,Vectra 4C, Chattanooga Group, Inc., Hixson, TN

5. **Device Description:** The SRT II Muscle Stimulator is comprised of the following main components:

A system console including software and control electronics;
A control and display panel;
Device accessories including Muscle Stimulator electrodes and cables.

The SRT II Device is a 4 mode, 10-channel unit for muscle stimulation housed in a portable case. The microprocessor controlled SRT II Device provides Muscle Stimulator alternating current with enhanced reliability and user friendly interface.

The user friendly interface and its display provides operator information about operation mode and signal intensities.

6. **Intended Use:** (Same as those for predicate device)

1. Relaxation of muscle spasms
2. Prevention or retardation of disuse atrophy
3. Increasing local blood circulation
4. Muscle re-education
5. Immediate post-surgical stimulation of calf muscles to prevent thrombosis
6. Maintaining or increasing range of motion

Non-Clinical Tests Submitted

Guidance and Manufacturer's Declaration—Electromagnetic Emissions

Emissions Test	Compliance	Guidance
RF Emissions CISPR 11	Group 1	This Product only uses RF energy for its internal functions. Therefore, its RF emissions are low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	This Product is suitable for use in establishments other than domestic and those directly connected to public low-voltage power supply networks
Harmonic Emissions IEC 61000-3-2	N/A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	N/A	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Guidance
Electrostatic Discharge IEC 61000- 4-2	± 6 kV Contact ± 8 kV Air	± 6 kV Contact ± 8 kV Air	relative humidity should be at least 30%.
Radiated RF IEC 61000-4-3	3 Vrms 3 Vrms	80 MHz to 2.5 GHz 80 MHz to 2.5 GHz	Portable and mobile RF communications equipment should not be used at close distances
Electrical Fast Transient/ Burst IEC 61000-4-4	± 2 kV on power Supply Lines ± 1 kV on Input/Output Lines	± 2 kV on Power Supply Lines ± 1 kV on Input/Output Lines	Mains power quality should be that of a typical commercial or hospital environment

Clinical Tests Submitted

None

Conclusion

The SRT II Muscle Stimulator has the same intended use and similar characteristics as the muscle stimulation predicate devices. Moreover, bench testing and non-clinical testing documentation supplied in this submission demonstrates that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the Therapeutic Innovations SRT II Muscle Stimulator is substantially equivalent to the muscle stimulation predicate devices.

Indications for Use

510(k) Number (if known): K071677

Device Name: SRT® II

Indications for Use:

1 Relaxation of muscle spasms;
2 Prevention or retardation of disuse atrophy;
3 Increasing local blood circulation;
4 Muscle re-education;
5 post-surgical stimulation of calf muscles to prevent venous thrombosis; and
6 Maintaining or increasing range of motion.

Prescription Use X_____ AND/OR Over-The Counter Use_____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071677

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Therapeutic Innovations, Inc.
% Mr. Howard K. Mann
Official Correspondent
8903 Spruce Mill Drive
Yardley, Pennsylvania 19067

Re: K071677
Trade Name: SRT II Muscle Stimulator
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF
Dated: June 6, 2008
Received: June 9, 2008

JUL 11 2008

Dear Mr. Mann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071677

Device Name: SRT® II

Indications for Use:

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